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10/551,295

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EXAMINER

SIGLER, JAY R

ART UNIT

PAPER NUMBER

3733

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                            |  |
|------------------------------|--------------------------------------|--------------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/551,295 | <b>Applicant(s)</b><br>YOUNG, ROBERT ALLAN |  |
|                              | <b>Examiner</b><br>JAY R. SIGLER     | <b>Art Unit</b><br>3733                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-14 and 16-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-14 and 16-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **35** and **37** (see page 5, paragraph beginning on line 15; from amendment of 14 April 2008). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

2. Claims 1 and 38 objected to because of the following informalities: in claim 1, line 2: "complex aperture each complex aperture" is suggested to be --complex aperture, wherein each complex aperture"; in claim 38, "he bone plate" appears to be a typographical error. Appropriate correction is required.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 32, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 14, and 15 of copending Application No. 10/809,034 (hereinafter "App 034"). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 32, and 33 are generic to all that is recited in claims 1, 7, 14, and 15 of App 034. Thus the invention of the App 034 claims is in effect a "species" of the "generic" invention of the instant application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the instant application claims are anticipated by the claims of App 034, the two sets of claims are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

5. Claims 1-4, 6-14, and 16-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Concerning claims 1, 32, and 34-37, the term “necked down portion” is not clearly defined in the specification or drawings and therefore it is unclear what limitation this adds to the claims.

7. Claim 6 recites the limitation “the threaded aperture” in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 16-18 are dependent on cancelled claim 15. Claims 16-18 only recite limitations that have been previously claimed. Therefore, they will be considered withdrawn from further examination.

9. Claim 33 recites the limitation “with the multi-faceted surface” in line 2. There is insufficient antecedent basis for this limitation in the claim.

10. In claim 28, the language “wherein the set is comprised of three overlapping holes” appears to contradict the language from claim 1 “at least one set of two overlapping holes”.

11. Generally, the amended claim language appears to make the dependent claim limitations unclear because the language used for the limitations is not consistent. Applicant is requested to amend the dependent claims to be consistent with the language used in any previously or consequently amended independent claims.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-3, 6-8, 10-13, 15, 19-22, 24-26, 28-30, 32, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (U.S. Patent 6,406,478; previously cited) in view of Weaver et al. (U.S. Patent 6,623,486).

Concerning claim 1, Kuo teaches a **bone plate** (see Fig. 1) **with a longitudinal axis, a bone-contacting bottom side and a top side with at least one complex aperture (22) each complex aperture comprised of at least one set of two overlapping holes having an offset of a given distance between centers thereof** (col. 2, l. 36-38), **such offset defining a necked down portion** (see Fig. 1) **between the overlapping holes, each such set of overlapping holes communicating through the plate from the top to the bottom side.** Kuo does not specifically teach that the holes are threaded.

However, Weaver et al. teaches a bone plate with holes 56 that are threaded in order to allow the use of locking screws (see Abstract) which provide a better engagement between bone plate and bone screw. It would have been obvious to someone of ordinary skill in the art at the time of the invention to thread the overlapping holes in the invention of Kuo, in view of Weaver et al., in order to

allow the use of locking screws (see Abstract) and consequently provide a better engagement between bone plate and bone screw.

Concerning claim 6, the bone plate of Kuo includes multiple holes as seen in Figure 1. Concerning claim 10 and 11, the holes can be considered aligned on an axis or in a staggered arrangement from the longitudinal axis. Concerning claims 19 and 20, the modified holes would have been adapted to receive a bone screw (20 in Weaver et al.) with head and bone-engaging thread and the head of the bone screw has a plate engaging thread.

Concerning claims 24 and 28, the overlapping holes of Kuo are comprised of two or three overlapping holes.

Concerning claims 2, 3, 7, 8, 12, 13, 21, 22, 25, 26, 29, and 30, Kuo teaches the holes formed normal to the top of the plate (see Fig. 3). Figures 12, 15 and 16 of Weaver et al. show the holes being formed at angles normal to the top side of the plate or at an angle offset from normal to the top side of the plate in order to allow the bone screws to enter the bone at different angles. It would have been obvious to someone of ordinary skill in the art at the time of the invention to have the modified holes of Kuo at angles, in view of Weaver et al., in order to allow the bone screws to enter the bone at different angles.

Concerning claim 32, Kuo, in view of Weaver et al., fairly suggests the bone plate and bone screw as shown above.

Concerning claims 34 - 36, Kuo, in view of Weaver et al., fairly suggests the limitations as shown above.

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14. Claims 4, 9, 14, 18, 23, 27, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (U.S. Patent 6,406,478) in view of Weaver et al. (U.S. Patent 6,623,486) as applied to claims 1, 6, 11, 19, 24, or 28 above, and further in view of Orbay (U.S. Patent 6,358,250). Kuo, in view of Weaver et al., fairly suggests the invention as claimed (shown above) but does not fairly suggest wherein at least one of the overlapping holes is formed normal to the top side of the plate and at least a second of the overlapping holes is formed at an angle offset from normal to the top side of the plate. Orbay teaches a bone plate with holes that define axes which are oblique relative to each other (Column 3, Lines 52-58; Figure 6, Axes A<sub>1</sub>-A<sub>4</sub>) to secure the bone fragments in their proper orientation (Column 4, Lines 48-53). It would have been obvious to someone of ordinary skill in the art at the time of the invention to use the holes with axes which are oblique of Orbay in the invention of Kuo, in view of Weaver et al., in order to secure the bone fragments in their proper orientation.

15. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (U.S. Patent 6,406,478) in view of Weaver et al. (U.S. Patent 6,623,486) as applied to claim 32 above, and further in view of Cesarone (U.S. Patent 5,851,207). Kuo, in view of Weaver et al., fairly suggests the invention as claimed (shown above) but does not fairly suggest including a drill guide that is securely engageable to the bone plate. Cesarone teaches a bone plate and drill guide that are securable to one another (Column 3, Lines 48-49) because the locking mechanism demands extremely precise screw alignment and, thus, accurate drill guides are critical to successful operations (Column 1, Lines 59-67). It would have been obvious to someone of ordinary skill in the



art at the time of the invention to include a securable drill guide in the modified invention of Kuo, in view of Weaver et al. and Cesarone, because the locking mechanism demands extremely precise screw alignment and, thus, accurate drill guides are critical to successful operations.

16. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (U.S. Patent 6,406,478) in view of Weaver et al. (U.S. Patent 6,623,486) and Tepic et al. (U.S. Patent 5,733,287).

Concerning claim 37, Kuo, in view of Weaver et al., fairly suggests the claimed invention as applied to claim 1 in paragraph 6 above, but does not fairly suggest wherein the bottom side includes recesses located between adjacent threaded apertures and which are substantially located exclusively on the bottom side, the recesses being sized so as to define a cross-section transverse to the longitudinal axis and across the recesses that ensures that a yield strength in bending across the recesses is less than across a threaded aperture. Tepic et al. teaches a bone plate with recesses 13 that are located on the bottom side to reduce the peak stresses (Column 1, Lines 34-36). It would have been obvious to someone of ordinary skill in the art at the time of the invention to include the recesses of Tepic et al. in the modified invention of Kuo, in view of Weaver et al., in order to reduce the peak stresses.

Concerning claim 38, the recesses of Tepic et al. are substantially rectangular in form (taken to be embodied by the fact that the cross section of the recess would be the same as the cross section 15 which is substantially

rectangular, or alternatively embodied by the recesses are taken to be cut out at substantially right angles from the sides and top).

Concerning claim 39, the recesses of Tepic et al. are equally spaced along the longitudinal axis (seen in Figure 8).

Concerning claim 40, Tepic teaches that the total area removed from the bottom side due to the recesses is less than 50% of the total surface area of the bottom side (Seen in Figure 2 where there is no transverse recesses, the total area removed is equal to 0%).

Concerning claim 41, the recesses of Tepic et al. are transverse and extend across the width of the bone plate (Column 2, Lines 58-59).

1. Claims 37, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (U.S. Patent 6,406,478) in view of Weaver et al. (U.S. Patent 6,623,486) and Klau et al. (U.S. Patent 5,002,544).

Concerning claim 37, Kuo, in view of Weaver et al., fairly suggests the claimed invention as applied to claim 1 in paragraph 6 above, but does not fairly suggest wherein the bottom side includes recesses located between adjacent threaded apertures and which are substantially located exclusively on the bottom side, the recesses being sized so as to define a cross-section transverse to the longitudinal axis and across the recesses that ensures that a yield strength in bending across the recesses is less than across a threaded aperture. Klau et al. teaches a bone plate with recesses 10 that are located on the bottom side to allow the resistance to bending in these areas to be less than in the area of the

holes (Column 1, Lines 49-52). It would have been obvious to someone of ordinary skill in the art at the time of the invention to include the recesses of Klau et al. in the modified invention of Kuo, in view of Weaver et al., in order to allow the resistance to bending in these areas to be less than in the area of the holes.

Concerning claim 42, the recesses of Klau et al. extend from a side of the bone plate transversely toward the longitudinal axis but not across the axis (seen in Figure 9).

### ***Response to Arguments***

17. Applicant's arguments with respect to claims 1-4, 5-14, and 16-42 have been considered but are moot in view of the new ground(s) of rejection.

18. In response to applicant's argument that bone plate for the human spine is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, they are both bone plates and are considered to be in the same field of endeavor, which would be generally the medical arts and more specifically orthopedics.

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733